

## § 423.2112

limit its consideration of the ALJ's action to those exceptions raised by CMS or the IRE.

(d) *MAC's action.* (1) If the MAC decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The MAC may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request.

(3) The MAC must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The MAC may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the MAC declines to review a decision or dismissal on its own motion, the ALJ's decision or dismissal is binding.

### § 423.2112 Content of request for review.

(a)(1) The request for MAC review must be filed with the entity specified in the notice of the ALJ's action.

(2) The request for review must be in writing and may be made on a standard form, except for requests for expedited reviews which may be made orally.

(3) The MAC must document all oral requests in writing and maintain the documentation in the case file.

(4) A written request that is not made on a standard form or, for expedited requests, an oral request, is accepted if it includes the enrollee's name and telephone number, the plan name; Medicare health insurance claim number; the ALJ appeal number; the specific Part D drug(s) for which the review is requested; a statement that the enrollee is requesting an expedited review, if applicable; and the name and signature of the enrollee or the representative of the enrollee.

(b) The request for review must identify the parts of the ALJ action with which the enrollee requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dis-

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missal, or other determination being appealed.

(c) The MAC will limit its review of an ALJ's actions to those exceptions raised by the enrollee in the request for review, unless the enrollee is unrepresented. For purposes of this section only, a representative is either anyone with a valid appointment as the enrollee's representative or is a member of the enrollee's family, a legal guardian or an individual who routinely acts on behalf of the enrollee, such as a family member or friend who has a power of attorney.

### § 423.2114 Dismissal of request for review.

The MAC dismisses a request for review if the enrollee requesting review did not file the request within the stated period of time and the time for filing has not been extended. The MAC also dismisses the request for review if—

(a) The enrollee asks to withdraw the request for review;

(b) The individual or entity does not have a right to request MAC review; or

(c) The enrollee died while the request for review is pending and the enrollee's estate or representative, if any, either has no remaining financial interest in the case or does not want to continue the appeal.

### § 423.2116 Effect of dismissal of request for MAC review or request for hearing.

The dismissal of a request for MAC review or denial of a request for review of a dismissal issued by an ALJ is binding and not subject to further review unless reopened and vacated by the MAC. The MAC's dismissal of a request for hearing is also binding and not subject to judicial review.

### § 423.2118 Obtaining evidence from the MAC.

An enrollee may request and receive a copy of all or part of the record of the ALJ hearing, including the exhibits list, documentary evidence, and a copy of the CD of the oral proceedings. However, the enrollee may be asked to pay the costs of providing these items. If an enrollee requests evidence from the MAC and an opportunity to comment

on that evidence, the time beginning with the MAC's receipt of the request for evidence through the expiration of the time granted for the enrollee's response will not be counted toward the adjudication deadline.

**§ 423.2120 Filing briefs with the MAC.**

Upon request, the MAC will give the enrollee requesting review a reasonable opportunity to file a brief or other written statement about the facts and law relevant to the case. Unless the enrollee requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the MAC will not be counted toward the adjudication timeframe set forth in § 423.2100. The MAC may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to file a brief or position paper if the MAC determines that it is necessary to resolve the issues in the case. The MAC cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor either participates, or decides not to participate in MAC review.

**§ 423.2122 What evidence may be submitted to the MAC.**

(a) *Appeal before the MAC on request for review of ALJ's decision.* (1) If the MAC is reviewing an ALJ's decision, the MAC will consider the evidence contained in the record of the proceedings before the ALJ, and any new evidence that relates to the period before the coverage determination. If the hearing decision decides a new issue that the enrollee was not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue that is submitted with the request for review.

(2) If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.

(3) The MAC will not consider any new evidence submitted regarding a change in condition of an enrollee after

a coverage determination is made. The MAC will remand a case to the Part D IRE if the MAC determines that the enrollee wishes to have evidence on his or her change in condition after the coverage determination considered.

(b) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, the MAC may, on its own initiative, issue subpoenas requiring an enrollee or Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. The MAC may not issue a subpoena to CMS, or the IRE to compel the production of evidence.

(1) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality or undue burden, was made before the MAC, the Secretary may review immediately that subpoena or a portion of the subpoena.

(2) Upon notice to the MAC that an enrollee or Part D plan sponsor intends to seek the Secretary review of the subpoena, the MAC must stay all proceedings affected by the subpoena, tolling the time period for the MAC to issue a final action or remand a case in response to a request for review for 15 calendar days or until the Secretary makes a decision with respect to the review request, whichever occurs first.

(3) If the Secretary does not grant review within the time allotted for the stay, the stay is lifted and the subpoena stands.

(c) *Enforcement.* (1) If the MAC determines that an enrollee or other person or entity subject to a subpoena issued under this section has refused to comply with the subpoena, the MAC may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) After submitting the enforcement request, the time period for the MAC to issue a final action or remand a case in response to a request for review is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.